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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,823	10/23/2003	David Grewe	CRD1061CIP1	6328

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,823	<b>Applicant(s)</b> GREWE ET AL.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/2006 has been entered.

### ***Notice of Amendment***

2. In response to the amendment filed on 09/11/2006, amended claim(s) 18 is/are acknowledged. The current rejections of the claim(s) 1-39 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al (US 2002/0165534 A1) in view of Klima et al (US 6,273,876 B1).

6. For claims 1, 19, and 23 Hayzelden et al teaches a bi-directional steerable guidewire, an intravascular device, having a deflectable tip, comprising:

- an elongated flexible tubing (22) defining a lumen (28) member having proximal (26) and distal portions (24);
- a flexible helical coil (82) having multiple turns and having proximal and distal ends (as best seen in Figures 2 and 3);
- an elongated deflection member (124 and 56) having proximal and distal portions and being slidably disposed within said tubing and within said helical coil (as best seen in Figures 5 and 8), the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member being flattened to form a deflection ribbon which extends in a plane (paragraph 43);
- a retaining ribbon (54) having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and
- an attachment member (50), a rounded bead, engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining

ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction (as best seen in Figure 2).

7. Hayzelden et al discloses the claimed invention except for the helical coil having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, the proximal end of said helical coil is attached to the distal portion of the flexible tubing, and wherein said undulations are lateral to the length of the elongated flexible tubing. Klima et al teaches a catheter, an intravascular device, having a helical coil (72i) having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil, the proximal end of said helical coil is attached to the distal portion of the flexible tubing, and wherein said undulations are lateral to the length of the elongated flexible tubing (column 10 lines 25-58 and as best seen in Figures 13B and 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Hayzelden et al, with the helical coil configuration as taught by Klima et al for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature.

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8. For claims 2-4, 20-22, and 24-26, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the continuous undulations take the form of a sinusoidal wave (as best seen in Figures 11A, 11B, 12A, 12B and 15) and a square sinusoidal wave (as best seen in Figures 13A, 13B, and 15) having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns, wherein the helical coil has a square cross-sectional configuration.

9. For claims 5 and 27, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon and the deflection ribbon are capable of being normally biased in an arcuate configuration causing the distal end of the helical coil to be normally biased in a curved shape due to being a shape-memory metallic alloy (Hayzelden et al, paragraph 43).

10. For claims 6 and 28, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of said deflection member is capable of being a circular cross section that extends from the proximal portion of the flexible tubing to approximately the distal portion of the tubing by not being entirely flattened (Hayzelden et al, paragraph 43).

11. For claim 7, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal end of said retaining ribbon extends from the distal portion of the flexible tubing to approximately the distal end of the flexible helical coil (Hayzelden et al, Figure 1).

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12. For claim 8, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50).

13. For claim 9, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the rounded bead is formed with an epoxy material ((Hayzelden et al, paragraph 30).

14. For claims 10 and 29, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50) which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon (56) engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

15. For claims 11 and 30, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

16. For claims 12 and 31, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon (Hayzelden et al, Figure 6).

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17. For claims 13 and 32, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection member and the retaining ribbon are joined to each other within the rounded bead (Hayzelden et al, Figures 2 and 5).

18. For claim 14, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element (54).

19. For claims 15 and 33, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration (54) to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other ((Hayzelden et al, Figures 2, 5 and 6).

20. For claims 16 and 34, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is formed by flattening an intermediate portion of the deflection member and the retaining ribbon is formed by flattening a distal portion of the deflection member (Hayzelden et al, paragraph 43).

21. For claims 17 and 35, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon is capable of having a thickness that is less than the thickness of the deflection ribbon via extra flattening (Hayzelden et al, paragraph 43).



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22. For claim 18, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is capable of having a thickness of .002 inches and the retaining ribbon is of a thickness of .0015 inches.

23. For claim 36, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle (42) and the elongated deflection member is mounted with the control handle for longitudinal movement (Hayzelden et al, Figure 1).

24. For claim 37, Hayzelden et al in view of Klima et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein said control handle includes a movable knob (78) that is coupled to the elongated deflection member for longitudinal positioning of the deflection member.

25. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al in view of Klima et al and in further view of Palermo (US 4,886,067). Hayzelden et al in view of Klima et al discloses the claimed invention except for the control handle coupled to the elongated flexible tubing with a release mechanism and the elongated deflection member extending through the entire length of the control handle and beyond the proximal end of the control handle. Palermo teaches an intravascular device (12) with a control handle (53) coupled to the elongated flexible tubing with a release mechanism (70) and an elongated deflection member (44) extending through the entire length of the control handle and beyond the proximal end

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of the control handle (as best seen in Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Hayzelden et al in view of Klima et al, with the handle configuration as taught by Palermo for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature.

### ***Response to Arguments***

26. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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